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ALFACELL CORP  
Form 424B3  
February 07, 2005

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REGISTRATION NO. 333-112865

PROSPECTUS, DATED FEBRUARY 7, 2005

ALFACELL CORPORATION  
12,294,217 Shares  
Common Stock

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Our securityholders named on page 15 of this prospectus are offering an aggregate of 12,294,217 shares of our Common Stock.

Our Common Stock is traded on the NASDAQ SmallCap Market under the symbol "ACEL." On February 4, 2005, the reported last sale price of our Common Stock on the NASDAQ SmallCap Market was \$3.50 per share.

INVESTING IN OUR COMMON STOCK IS SPECULATIVE AND INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 4.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is February 7, 2005

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ALFACELL CORPORATION

We are a biopharmaceutical company primarily engaged in the discovery and development of a new class of therapeutic drugs for the treatment of cancer and other pathological conditions. Based on our proprietary Ribonuclease, or RNase, which is a type of biological enzyme that splits RNA molecules and is the basis of our technology platform, our drug discovery and development program consists of novel therapeutics developed from amphibian ribonucleases. These are very basic RNA enzymes which play important roles in nature in the development of an organism's cells and in cell functions. RNA is an essential bio-chemical cellular component necessary to support life. There are various types of RNA,

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all of which have specific functions in a living cell. They help control several essential biological activities, namely regulation of cell proliferation, maturation, differentiation and cell death. Therefore, they are ideal candidates for the development of therapeutics for cancer and other life-threatening diseases, including HIV and autoimmune diseases, that require anti-proliferative and apoptotic, or programmed cell death, properties. We have co-sponsored and been a key participant in the International Ribonuclease Meetings held every three years. This is a conference on all facets of research and development in connection with ribonucleases that is attended by scientists from around the world.

Alfacell Corporation was incorporated in Delaware in 1981. Our corporate headquarters is located at 225 Belleville Avenue, Bloomfield, New Jersey 07003 and our telephone number is (973) 748-8082.

### OVERVIEW

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ONCONASE(R), our trademark name for our flagship product, is currently in an international, centrally randomized Phase III trial. The first part of the trial has been completed and the second confirmatory part of the trial is ongoing for which patient enrollment is expected to be completed in the first calendar quarter of 2005. The primary endpoint of the trial is survival, and as such, a sufficient number of deaths must occur in order to perform the required statistical analyses to determine the efficacy of ONCONASE(R) in patients with unresectable (inoperable) malignant mesothelioma. If the results of the clinical trials are positive, we expect to file for marketing registrations (NDA and MAA) for ONCONASE(R) within six months of completion of the statistical analyses. However, at this time, we cannot predict with certainty when a sufficient number of deaths will occur to achieve statistical significance. Hence, the timing of the filing is data driven as to when we will be able to file for marketing registrations in the US and EU. Therefore, we cannot predict with certainty what our total cost will be associated with obtaining marketing approvals, or when and if such approvals will be granted, and when actual sales will occur. We have also conducted other randomized and non-randomized trials with patients with advanced stages of solid tumors in other types of cancers.

ONCONASE(R), unlike most cancer drugs that attack all cells regardless of their phenotype (physical characteristics), malignant versus normal, and produce a variety of severe toxicities, is not an indiscriminate cytotoxic, or cell killing agent, but rather, its activity is controlled through unique and specific molecular mechanisms. ONCONASE(R) primarily affects extremely rapidly growing malignant cells. ONCONASE(R) is a novel amphibian ribonuclease, unique among the superfamily of pancreatic ribonuclease that has been isolated from the eggs of the RANA PIPIENS frog, commonly called the leopard frog. We have determined that thus far, ranpirnase, the generic name of ONCONASE(R), is the smallest known protein belonging to the superfamily of pancreatic ribonuclease and has been shown, on a molecular level, to re-regulate the unregulated growth and proliferation of cancer cells.

In December 2002, we received Fast Track Designation from the FDA for ONCONASE(R) for the treatment of malignant mesothelioma. Fast Track Designation is an FDA program designed to expedite the review of new drugs that are intended to treat serious or life threatening conditions and that

demonstrate the potential to address unmet medical needs. In February 2001, we received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or the EMEA. Orphan Medicinal Product Designation is a program designed to provide marketing,

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protocol and other incentives for pharmaceutical companies to develop and market products in the European Community that address life threatening or very serious conditions that affect not more than 5 in 10,000 persons in the European Community. Orphan designation in Europe entitles the Company to 10 years of marketing exclusivity, reduced filing fees and regulatory guidance from the EMEA.

These FDA and EMEA designations for ONCONASE(R) may serve to expedite its regulatory review, assuming the clinical trials yield a positive result. Future clinical trials, however, may not demonstrate that ONCONASE(R) is effective. Thus, our applications for FDA or EMEA approval to market ONCONASE(R), which are dependent upon the success of our clinical trials, may be affected. The efficacy and safety of ONCONASE(R) for malignant mesothelioma, will ultimately be determined by the FDA. In the interim, our Fast Track Designation allows us to continue to have meetings and discussions with the FDA to establish mutually agreed upon parameters for the NDA to obtain marketing approval for ONCONASE(R), based on the assumption that the clinical trials will continue to yield favorable results.

Our drug discovery program forms the basis for the development of specific recombinant RNases for chemically linking drugs and other compounds such as monoclonal antibodies, growth factors, etc. and gene fusion products with the goal of targeting various molecular functions. This program provides for joint design and generation of new products with outside partners. We may own these new products along with a partner(s), or we may grant an exclusive license to the collaborating partner(s).

We have also discovered another series of proteins, collectively named amphinases, that may have therapeutic uses. These proteins are bioactive in that they have an effect on living cells and organisms and have both anti-cancer and anti-viral activity. All of the proteins characterized to date are RNases. These products are currently undergoing preclinical testing. We are currently in discussions with potential pharmaceutical partners for the development of these new compounds as conjugates and fusion proteins.

We are engaged in the research, development and clinical trials of our products both independently and through research collaborations. Due to our lack of commercially available products, we have financed our operations since inception through the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through debt financings, the sale of our tax benefits and research products, interest income and financing received from our Chief Executive Officer. These funds provide us with the resources to acquire staff, facilities, capital equipment, finance our technology, product development, manufacturing and clinical trials. We have incurred losses since inception and to date we have not consummated any licensing, marketing or development arrangements. Presently, our cash balance is sufficient to fund our expanded operations at least through October 31, 2005 based on our expected level of expenditures in relation to activities in preparing ONCONASE(R) for an NDA filing and other ongoing operations of the company. However, we continue to seek additional capital financing through the sale of equity in private placements, sale of our tax benefits and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements that are based on current

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expectations, estimates and projections about our industry, management's beliefs, and assumptions made by management. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," and variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any forward-looking statements. The risks and uncertainties include those noted in "Risk Factors" below and in the documents incorporated by reference.

We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent that we are required to do so by law. We also may make additional disclosures in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K that we may file from time to time with the Securities and Exchange Commission, or SEC. Please also note that we provide a cautionary discussion of risks and uncertainties under the section entitled "Risk Factors" in our Annual Report on Form 10-K. These descriptions and statements are based on management's current expectations. Our actual results may differ significantly from the results discussed in these forward-looking statements as a result of certain factors, including those set forth in the "Risk Factors" section and elsewhere in this prospectus.

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### RISK FACTORS

AN INVESTMENT IN OUR COMMON STOCK IS SPECULATIVE AND INVOLVES A HIGH DEGREE OF RISK AND OUR BUSINESS IS SUBJECT TO A NUMBER OF RISKS, SOME OF WHICH ARE DISCUSSED BELOW. OTHER RISKS ARE PRESENTED ELSEWHERE IN THIS PROSPECTUS AND IN THE INFORMATION INCORPORATED BY REFERENCE INTO THIS PROSPECTUS. BEFORE DECIDING TO INVEST IN OUR COMPANY OR TO MAINTAIN OR INCREASE YOUR INVESTMENT, YOU SHOULD CAREFULLY CONSIDER THE RISKS DESCRIBED BELOW, IN ADDITION TO THE OTHER INFORMATION CONTAINED IN THIS PROSPECTUS, OUR ANNUAL REPORT ON FORM 10-K FOR THE FISCAL YEAR ENDED JULY 31, 2004, OUR QUARTERLY REPORT ON FORM 10-Q FOR THE FISCAL QUARTER ENDED OCTOBER 31, 2004; AND IN OUR OTHER FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION (THE "SEC"), INCLUDING ANY SUBSEQUENT REPORTS FILED ON FORMS 10-K, 10-Q AND 8-K. IF ANY OF THE FOLLOWING RISKS ACTUALLY OCCUR, OUR BUSINESS AND OPERATING RESULTS COULD BE HARMED. THIS COULD CAUSE THE TRADING PRICE OF OUR COMMON STOCK TO DECLINE, AND YOU MAY LOSE ALL OR PART OF YOUR INVESTMENT.

#### RISK RELATED TO OUR COMPANY

WE HAVE INCURRED LOSSES SINCE INCEPTION AND ANTICIPATE THAT WE WILL INCUR CONTINUED LOSSES FOR THE FORESEEABLE FUTURE. WE DO NOT HAVE A CURRENT SOURCE OF PRODUCT REVENUE AND MAY NEVER BE PROFITABLE.

We are a development stage company and since our inception our source of working capital has been public and private sales of our stock. We incurred a net loss of approximately \$1,081,000 for the three months ended October 31, 2004. We have continued to incur losses since July 2004. We may never achieve revenue sufficient for us to attain profitability.

We incurred net losses of approximately \$5,070,000, \$2,411,000 and \$2,591,000 for the fiscal years ended July 31, 2004, 2003 and 2002, respectively.

Our profitability will depend on our ability to develop, obtain

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regulatory approvals for, and effectively market ONCONASE(R) as well as entering into strategic alliances for the development of new drug candidates from the out-licensing of our proprietary RNase technology. The commercialization of our pharmaceutical products involves a number of significant challenges. In particular our ability to commercialize ONCONASE(R) depends on the success of our clinical development programs, our efforts to obtain regulatory approval and our sales and marketing efforts or those of our marketing partners, if any, directed at physicians, patients and third-party payors. A number of factors could affect these efforts including:

- o Our ability to demonstrate clinically that our products have utility and are safe;
- o Delays or refusals by regulatory authorities in granting marketing approvals;
- o Our limited financial resources relative to our competitors;
- o Our ability to obtain an appropriate marketing partner;
- o The availability and level of reimbursement for our products by third party payors;
- o Incidents of adverse reactions to our products;
- o Side effects or misuse of our products and unfavorable publicity that could result; and
- o The occurrence of manufacturing or distribution disruptions.

We will seek to generate revenue through licensing, marketing and development arrangements prior to receiving revenue from the sale of our products. To date we have not consummated any licensing or marketing arrangements and we may not be able to successfully consummate any such arrangements. We have entered into several development arrangements, which have resulted in limited revenues for us. However, we cannot ensure that these arrangements or future arrangements, if any, will result in

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significant amounts of revenue for us. We, therefore, are unable to predict the extent of any future losses or the time required to achieve profitability, if at all.

WE NEED ADDITIONAL FINANCING TO CONTINUE OPERATIONS, WHICH MAY NOT BE AVAILABLE ON ACCEPTABLE TERMS, IF IT IS AVAILABLE AT ALL.

We need additional financing in order to continue operations, including completion of our current clinical trials and filing marketing registrations for ONCONASE(R) in the United States with the FDA and in Europe with the EMEA. If the results from our current clinical trial do not demonstrate the efficacy and safety of ONCONASE(R) for malignant mesothelioma, our ability to raise additional capital will be adversely affected. Even if regulatory applications for marketing approvals are filed, we will need additional financing to continue operations. In connection with the recent private placement from which we realized \$10.0 million in gross proceeds from an institutional investor, we plan to expand our operations in preparing ONCONASE(R) for marketing registrations in the US and outside the US as well as fund our ongoing operations. Presently, our cash balance is sufficient to fund our expanded operations at least through October 31, 2005, based on our expected level of expenditures. However, taking

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into consideration all of the uncertainties related to drug development and our industry, we continue to seek additional capital financing through the sale of equity in private placements, sale of our net operating loss carryforwards and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all.

WE MAY BE UNABLE TO SELL CERTAIN STATE TAX BENEFITS IN THE FUTURE AND IF WE ARE UNABLE TO DO SO, IT WOULD ELIMINATE A SOURCE OF FINANCING THAT WE HAVE RELIED ON IN THE PAST.

At July 31, 2004, we had federal net operating loss carryforwards of approximately \$47,326,000 that expire from 2005 to 2024. We also had research and experimentation tax credit carryforwards of approximately \$1,426,000 that expire from 2005 to 2024. New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net operating loss carryforwards, in order to obtain tax benefits. The aggregate amount of net operating loss carryforwards that New Jersey allows corporations to sell each state fiscal year (July 1st through June 30th) is determined annually and if New Jersey reduces such aggregate amount in any fiscal year we may be unable to sell some or all of our available net operating loss carryforwards as we have in the past. In addition, there is a limited market for these types of sales and we may not be able to find someone to purchase our net operating loss carryforwards for a reasonable price. Our historical results of operations have been improved by our sale of net operating loss carryforwards and if we continue to generate a limited amount of revenue and are unable in the future to sell our net operating loss carryforwards, our results of operations will be negatively impacted.

For the state fiscal year 2005 (July 1, 2004 to June 30, 2005), we had approximately \$1,335,000 total available net operating loss carryforwards that were saleable; of which New Jersey permitted us to sell approximately \$339,000. We received approximately \$288,000 from the sale of the \$339,000 of net operating loss carryforwards, which we recognized as tax benefits for the quarter ended October 31, 2004. For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), we had approximately \$1,378,000 of total available net operating loss carryforwards that were saleable; of which New Jersey permitted us to sell approximately \$261,000. In December 2003, we received approximately \$222,000 from the sale of the \$261,000 of net operating loss carryforwards, which we recognized as tax benefits for the fiscal year ended July 31, 2004.

If still available under New Jersey law, we will attempt to sell the remaining \$996,000 of our net operating loss carryforwards, between July 1, 2005 and June 30, 2006. This amount, which is a carryover of our remaining net operating loss carryforwards from state fiscal year 2005, may increase if we incur

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additional net losses and research and development credits during state fiscal year 2006. We can not estimate, however, what percentage of our saleable net operating loss carryforwards New Jersey will permit us to sell, how much money we will receive in connection with the sale, if we will be able to find a buyer for our net operating loss carryforwards or if such funds will be available in a timely manner.

WE CANNOT PREDICT HOW LONG IT WILL TAKE US NOR HOW MUCH IT WILL COST US TO COMPLETE OUR PHASE III TRIAL BECAUSE IT IS A SURVIVAL STUDY AND WE ARE STILL IN PATIENT ENROLLMENT IN PART TWO OF THIS PHASE III TRIAL.

We currently have ongoing a two-part Phase III trial of ONCONASE(R) as a

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treatment for malignant mesothelioma. The first part of the clinical trial has been completed and the second, confirmatory part is still ongoing for which patient enrollment is expected to be completed in the first calendar quarter of 2005. The primary endpoint of the Phase III clinical trial is survival, which tracks the length of time patients enrolled in the study live. According to the protocol, a sufficient number of patient deaths must occur in order to perform the required statistical analyses to determine the efficacy of ONCONASE(R) in patients with unresectable (inoperable) malignant mesothelioma. Since it is impossible to predict with certainty when these terminal events in the Phase III trial will occur, we do not have the capability of reasonably determining when a sufficient number of deaths will occur, nor when we will be able to file for marketing registrations with the FDA and EMEA.

In addition, clinical trials are very costly and time consuming. The length of time required to complete a clinical trial depends on several factors including the size of the patient population, the ability of patients to get to the site of the clinical study, and the criteria for determining which patients are eligible to join the study. Delays in patient enrollment, could delay achieving a sufficient number of deaths required for statistical analyses, which therefore may delay the marketing registrations. Although we believe we could modify some of our expenditures to reduce our cash outlays in relation to our clinical trials and other NDA related expenditures, we cannot quantify which or the amount such expenditures might be modified. Hence, a delay in the commercial sale of ONCONASE(R) would increase the time frame of our cash expenditure outflows and may require us to seek additional financing. Such capital financing may not be available on favorable terms or at all.

The FDA and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed pre-clinical and clinical testing and other costly and time consuming procedures. Satisfaction of these requirements typically takes several years depending on the type, complexity and novelty of the product. We cannot apply for FDA or EMEA approval to market ONCONASE(R) until the clinical trials and all other registration requirements have been met.

IF WE FAIL TO OBTAIN THE NECESSARY REGULATORY APPROVALS, WE WILL NOT BE ALLOWED TO COMMERCIALIZE OUR DRUGS AND WILL NOT GENERATE PRODUCT REVENUE.

The FDA and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed pre-clinical and clinical testing and other costly and time consuming procedures. Satisfaction of these requirements typically takes several years depending on the level of complexity and novelty of the product. Drugs in late stages of clinical development may fail to show the desired safety and efficacy results despite having progressed through initial clinical testing. While limited trials with our product have produced certain favorable results, we cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of any compound within any specific time period, if at all. Furthermore, the FDA or the company may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, we cannot apply for FDA or EMEA approval to market ONCONASE(R) until pre-clinical and

clinical trials have been completed. Several factors could prevent the successful completion or cause significant delays of these trials including an inability to enroll the required number of patients or failure to demonstrate

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the product is safe and effective in humans. Also if safety concerns develop, the FDA and EMEA could stop our trials before completion.

In December 2002, we received Fast Track Designation from the Food and Drug Administration, or the FDA for ONCONASE(R) for the treatment of malignant mesothelioma. In February 2001, we received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or the EMEA.

All statutes and regulations governing the conduct of clinical trials are subject to change by various regulatory agencies, including the FDA, in the future, which could affect the cost and duration of our clinical trials. Any unanticipated costs or delays in our clinical studies would delay our ability to generate product revenues and to raise additional capital and could cause us to be unable to fund the completion of the studies.

We may not market or sell any product for which we have not obtained regulatory approval. We cannot assure that the FDA or other regulatory agencies will ever approve the use of our products that are under development. Even if we receive regulatory approval, such approval may involve limitations on the indicated uses for which we may market our products. Further, even after approval, discovery of previously unknown problems could result in additional restrictions, including withdrawal of our products from the market.

If we fail to obtain the necessary regulatory approvals, we cannot market or sell our products in the United States, or in other countries and our long-term viability would be threatened. If we fail to achieve regulatory approval or foreign marketing authorizations for ONCONASE(R) we will not have a saleable product or product revenues for quite some time, if at all, and may not be able to continue operations.

WE ARE AND WILL BE DEPENDENT UPON THIRD PARTIES FOR MANUFACTURING OUR PRODUCTS. IF THESE THIRD PARTIES DO NOT DEVOTE SUFFICIENT TIME AND RESOURCES TO OUR PRODUCTS OUR REVENUES AND PROFITS MAY BE ADVERSELY AFFECTED.

We do not have the required manufacturing facilities to manufacture our products. We presently rely on third parties to perform certain of the manufacturing processes for the production of ONCONASE(R) for use in clinical trials. Currently, we contract with Scientific Protein Labs for the manufacturing of ranpirnase (protein drug substance) from the oocytes, or the unfertilized eggs, of the RANA PIPIENS frog, which is found in the Northwest United States and is commonly called the leopard frog. We contract with Ben Venue Corporation for the manufacturing of ONCONASE(R) and with Cardinal Health for the labeling, storage and shipping of ONCONASE(R) for clinical trial use. We utilize the services of these third party manufacturers solely on an as needed basis with terms and prices customary for our industry.

Our use of manufacturers for ranpirnase and ONCONASE(R) have been approved by the FDA. We have identified substantial alternative service providers for the manufacturing services for which we contract. In order to replace an existing service provider we must amend our IND to notify the FDA of the new manufacturer. Although the FDA generally will not suspend or delay a clinical trial as a result of replacing an existing manufacturer, the FDA has the authority to suspend or delay a clinical trial if, among other grounds, human subjects are or would be exposed to an unreasonable and significant risk of illness or injury as a result of the replacement manufacturer.

We intend to rely on third parties to manufacture our products if they



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are approved for sale by the appropriate regulatory agencies and are commercialized. Third party manufacturers may not be able to meet our needs with respect to the timing, quantity or quality of our products or to supply products on acceptable terms.

BECAUSE WE DO NOT HAVE MARKETING, SALES OR DISTRIBUTION CAPABILITIES, WE EXPECT TO CONTRACT WITH THIRD PARTIES FOR THESE FUNCTIONS AND WE WILL THEREFORE BE DEPENDENT UPON SUCH THIRD PARTIES TO MARKET, SELL AND DISTRIBUTE OUR PRODUCTS IN ORDER FOR US TO GENERATE REVENUES.

We currently have no sales, marketing or distribution capabilities. In order to commercialize any product candidates for which we receive FDA approval, we expect to rely on established third party strategic partners to perform these functions. For example, if we are successful in our Phase III clinical trials with ONCONASE(R), and are granted marketing approval for the commercialization of ONCONASE(R), we will be unable to introduce the product to market without establishing a marketing collaboration with a pharmaceutical company with those resources. If we establish relationships with one or more biopharmaceutical or other marketing companies with existing distribution systems and direct sales forces to market any or all of our product candidates, we cannot assure you that we will be able to enter into or maintain agreements with these companies on acceptable terms, if at all. Further, it is likely that we will have limited or no control over the manner in which product candidates are marketed or the resources devoted to such markets.

In addition, we expect to begin to incur significant expenses in determining our commercialization strategy with respect to one or more of our product candidates. The determination of our commercialization strategy with respect to a product candidate will depend on a number of factors, including:

- o the extent to which we are successful in securing collaborative partners to offset some or all of the funding obligations with respect to product candidates;
- o the extent to which our agreement with our collaborators permits us to exercise marketing or promotion rights with respect to the product candidate;
- o how our product candidates compare to competitive products with respect to labeling, pricing, therapeutic effect, and method of delivery; and
- o whether we are able to establish agreements with third party collaborators, including large biopharmaceutical or other marketing companies, with respect to any of our product candidates on terms that are acceptable to us.

A number of these factors are outside of our control and will be difficult to determine.

OUR PRODUCT CANDIDATES MAY NOT BE ACCEPTED BY THE MARKET.

Even if approved by the FDA and other regulatory authorities, our product candidates may not achieve market acceptance, which means we would not receive significant revenues from these products. Approval by the FDA does not necessarily mean that the medical community will be convinced of the relative safety, efficacy and cost-effectiveness of our products as compared to other products. In addition, third party reimbursers such as insurance companies and HMOs may be reluctant to reimburse expenses relating to our products.

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WE DEPEND UPON KUSLIMA SHOGEN AND OUR OTHER KEY PERSONNEL AND MAY NOT BE ABLE TO RETAIN THESE EMPLOYEES OR RECRUIT QUALIFIED REPLACEMENT OR ADDITIONAL PERSONNEL, WHICH WOULD HAVE A MATERIAL ADVERSE AFFECT ON OUR BUSINESS.

We are highly dependent upon our founder, Chairman and Chief Executive Officer, Kuslima Shogen. Kuslima Shogen's talents, efforts, personality, vision and leadership have been, and continue to be, critical to our success. The diminution or loss of the services of Kuslima Shogen, and any negative market or industry perception arising from that diminution or loss, would have a material adverse effect on our business. While our other employees have substantial experience and have made significant contributions to our business, Kuslima Shogen is our senior executive and also our primary supporter because she represents the Company's primary means of accessing the capital markets.

Because of the specialized scientific nature of our business, our continued success also is dependent upon our ability to attract and retain qualified management and scientific personnel. There is intense competition for qualified personnel in the pharmaceutical field. As our company grows our inability to attract qualified management and scientific personnel could materially adversely affect our research and development programs, the commercialization of our products and the potential revenue from product sales.

We do not have employment contracts with Kuslima Shogen or any of our other management and scientific personnel.

### RISK RELATED TO OUR INDUSTRY

OUR PROPRIETARY TECHNOLOGY AND PATENTS MAY OFFER ONLY LIMITED PROTECTION AGAINST INFRINGEMENT AND THE DEVELOPMENT BY OUR COMPETITORS OF COMPETITIVE PRODUCTS.

We own two patents jointly with the United States government. These patents expire in 2016. We also own ten United States patents with expiration dates ranging from 2006 to 2019, four European patents with expiration dates ranging from 2009 to 2016 and one Japanese patent that expires in 2010. We also own patent applications that are pending in the United States, Europe and Japan. The scope of protection afforded by patents for biotechnological inventions is uncertain, and such uncertainty applies to our patents as well. Therefore, our patents may not give us competitive advantages or afford us adequate protection from competing products. Furthermore, others may independently develop products that are similar to our products, and may design around the claims of our patents. Patent litigation and intellectual property litigation are expensive and our resources are limited. If we were to become involved in litigation, we might not have the funds or other resources necessary to conduct the litigation effectively. This might prevent us from protecting our patents, from defending against claims of infringement, or both. To date, we have not received any threats of litigation regarding patent issues.

DEVELOPMENTS BY COMPETITORS MAY RENDER OUR PRODUCTS OBSOLETE OR NON-COMPETITIVE.

In February 2004, the Food and Drug Administration granted Eli Lilly & Company approval to sell its Alimta(R) medication as an orphan drug to treat patients with pleural mesothelioma. Alimta is a multi-targeted antifolate that is based upon a different mechanism of action than ONCONASE(R). To our knowledge, no other company is developing a product with the same mechanism of action as ONCONASE(R). However, there may be other companies, universities, research teams or scientists who are developing products to treat the same medical conditions our products are intended to treat. Eli Lilly is, and some of these other companies, universities, research teams or scientists may be more experienced and have greater clinical, marketing and regulatory capabilities and managerial and financial resources

than we do. This may enable them to develop products to treat the same medical conditions our products are intended to treat before we are able to complete the development of our competing product.

Our business is very competitive and involves rapid changes in the technologies involved in developing new drugs. If others experience rapid technological development, our products may become obsolete before we are able to recover expenses incurred in developing our products. We will probably face new competitors as new technologies develop. Our success depends on our ability to remain competitive in the development of new drugs or we may not be able to compete successfully.

#### WE MAY BE SUED FOR PRODUCT LIABILITY.

Our business exposes us to potential product liability that may have a negative effect on our financial performance and our business generally. The administration of drugs to humans, whether in clinical trials or commercially, exposes us to potential product and professional liability risks which are inherent in the testing, production, marketing and sale of new drugs for humans. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance and materially adversely affect our business. We maintain product liability insurance to protect our products and product candidates in amounts customary for companies in businesses that are similarly situated, but our insurance coverage may not be sufficient to cover claims. Furthermore, liability insurance coverage is becoming increasingly expensive and we cannot be certain that we will always be able to maintain or increase our insurance coverage at an affordable price or in sufficient amounts to protect against potential losses. A product liability claim, product recall or other claim, as well as any claim for uninsured liabilities or claim in excess of insured liabilities, may significantly harm our business and results of operations. Even if a product liability claim is not successful, adverse publicity and time and expense of defending such a claim may significantly interfere with our business.

IF WE ARE UNABLE TO OBTAIN FAVORABLE REIMBURSEMENT FOR OUR PRODUCT CANDIDATES, THEIR COMMERCIAL SUCCESS MAY BE SEVERELY HINDERED.

Our ability to sell our future products may depend in large part on the extent to which reimbursement for the costs of our products is available from government entities, private health insurers, managed care organizations and others. Third-party payors are increasingly attempting to contain their costs. We cannot predict actions third-party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. Reduced or partial reimbursement coverage could make our products less attractive to patients, suppliers and prescribing physicians and may not be adequate for us to maintain price levels sufficient to realize an appropriate return on our investment in our product candidates or compete on price.

In some cases, insurers and other healthcare payment organizations try to encourage the use of less expensive generic brands and over-the-counter, or OTC, products through their prescription benefits coverage and reimbursement policies. These organizations may make the generic alternative more attractive to the patient by providing different amounts of reimbursement so that the net cost of the generic product to the patient is less than the net cost of a prescription brand product. Aggressive pricing policies by our generic product competitors and the prescription benefits policies of insurers could have a

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negative effect on our product revenues and profitability.

Many managed care organizations negotiate the price of medical services and products and develop formularies for that purpose. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization patient population. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those

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policies increasingly favor generic or OTC products, our market share and gross margins could be negatively affected, as could our overall business and financial condition.

The competition among pharmaceutical companies to have their products approved for reimbursement may also result in downward pricing pressure in the industry or in the markets where our products will compete. We may not be successful in any efforts we take to mitigate the effect of a decline in average selling prices for our products. Any decline in our average selling prices would also reduce our gross margins.

In addition, managed care initiatives to control costs may influence primary care physicians to refer fewer patients to oncologists and other specialists. Reductions in these referrals could have a material adverse effect on the size of our potential market and increase costs to effectively promote our products.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

There have been a number of legislative and regulatory proposals aimed at changing the healthcare system and pharmaceutical industry, including reductions in the cost of prescription products and changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products. For example, the Prescription Drug and Medicare Improvement Act of 2003 which was recently enacted. This legislation provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. Although we cannot predict the full effects on our business of the implementation of this new legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues. It is also possible that other proposals will be adopted. As a result of the new Medicare prescription drug benefit or any other proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could harm our ability to operate our business efficiently, obtain collaborators and raise capital.

### RISK RELATED TO THIS OFFERING

WE HAVE ONLY RECENTLY BEEN RELISTED ON THE NASDAQ SMALLCAP MARKET AND OUR STOCK IS THINLY TRADED AND YOU MAY NOT BE ABLE TO SELL OUR STOCK WHEN YOU WANT TO DO SO.

From April 1999, when we were delisted from Nasdaq, until September 9, 2004, when we were relisted on the Nasdaq SmallCap Market, there was no

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established trading market for our common stock. During that time, our common stock was quoted on the OTC Bulletin Board and was thinly traded. There is no assurance that we will be able to comply with all of the listing requirements necessary to maintain relisted on the Nasdaq SmallCap Market. In addition, our stock remains thinly traded and you may be unable to sell our common stock during times when the trading market is limited.

THE PRICE OF OUR COMMON STOCK HAS BEEN, AND MAY CONTINUE TO BE, VOLATILE.

The market price of our common stock, like that of the securities of many other development stage biotechnology companies, has fluctuated over a wide range and it is likely that the price of our common stock will fluctuate in the future. Over the past three years, the sale price for our common stock,

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as reported by Nasdaq and the OTC Bulletin Board has fluctuated from a low of \$0.18 to a high of \$10.07. The market price of our common stock could be impacted by a variety of factors, including:

- o announcements of technological innovations or new commercial products by us or our competitors,
- o disclosure of the results of pre-clinical testing and clinical trials by us or our competitors,
- o disclosure of the results of regulatory proceedings,
- o changes in government regulation,
- o developments in the patents or other proprietary rights owned or licensed by us or our competitors,
- o public concern as to the safety and efficacy of products developed by us or others,
- o litigation, and
- o general market conditions in our industry.

In addition, the stock market continues to experience extreme price and volume fluctuations. These fluctuations have especially affected the market price of many biotechnology companies. Such fluctuations have often been unrelated to the operating performance of these companies. Nonetheless, these broad market fluctuations may negatively affect the market price of our common stock.

EVENTS WITH RESPECT TO OUR SHARE CAPITAL COULD CAUSE THE PRICE OF OUR COMMON STOCK TO DECLINE.

Sales of substantial amounts of our common stock in the open market, or the availability of such shares for sale, could adversely affect the price of our common stock. We had 34,994,514 shares of common stock outstanding as of October 31, 2004. The following securities that may be exercised for, or are convertible into, shares of our common stock were issued and outstanding as of October 31, 2004:

- o Options. Stock options to purchase 3,331,245 shares of our common stock at a weighted average exercise price of approximately \$3.56 per share.

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- o Warrants. Warrants to purchase 11,564,853 shares of our common stock at a weighted average exercise price of approximately \$2.52 per share.
- o Convertible Notes. Notes which will convert into 1,424,822 shares of our common stock at an average conversion price of \$0.25 per share and warrants which are convertible into 1,624,822 shares of our common stock at an exercise price of \$1.00 per share.

The shares of our common stock that may be issued under the options, warrants and upon conversion of the notes are currently registered with the SEC or are eligible for sale without any volume limitations pursuant to Rule 144(k) under the Securities Act.

OUR INCORPORATION DOCUMENTS MAY DELAY OR PREVENT (I) THE REMOVAL OF OUR CURRENT MANAGEMENT OR (II) A CHANGE OF CONTROL THAT A STOCKHOLDER MAY CONSIDER FAVORABLE.

We are currently authorized to issue 1,000,000 shares of preferred stock. Our Board of Directors is authorized, without any approval of the stockholders, to issue the preferred stock and determine the terms of the preferred stock. This provision allows the board of directors to affect the rights of stockholders, since the board of directors can make it more difficult for common stockholders to replace members of the board. Because the board of directors is responsible for appointing the members of our management, these provisions could in turn affect any attempt to replace current management by the common stockholders. Furthermore, the existence of authorized shares of preferred stock might have the effect of discouraging any attempt by a person, through the acquisition of a substantial number of shares of common stock, to acquire control of our company. Accordingly, the accomplishment of a tender offer

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may be more difficult. This may be beneficial to management in a hostile tender offer, but have an adverse impact on stockholders who may want to participate in the tender offer or inhibit a stockholder's ability to receive an acquisition premium for his or her shares.

THE ABILITY OF OUR STOCKHOLDERS TO RECOVER AGAINST ARMUS HARRISON & CO., OR AHC, MAY BE LIMITED BECAUSE WE HAVE NOT BEEN ABLE TO OBTAIN THE REISSUED REPORTS OF AHC WITH RESPECT TO THE FINANCIAL STATEMENTS INCLUDED IN THIS PROSPECTUS FOR THE FISCAL YEAR ENDED JULY 31, 2004, NOR HAVE WE BEEN ABLE TO OBTAIN AHC'S CONSENT TO THE USE OF SUCH REPORT THEREIN.

Section 11 of the Securities Exchange Act of 1934 (the "Exchange Act") provides that any person acquiring or selling a security in reliance upon statements set forth in a registration statement may assert a claim against every accountant who has with its consent been named as having prepared or certified any part of the registration statement, or as having prepared or certified any report or valuation that is used in connection with the registration statement, if that part of the registration statement at the time it is filed contains a false or misleading statement of a material fact, or omits a material fact required to be stated therein or necessary to make the statements therein not misleading (unless it is proved that at the time of such acquisition such acquiring person knew of such untruth or omission).

In June 1996, AHC dissolved and ceased all operations. Therefore, we have not been able to obtain the reissued reports of AHC with respect to the financial statements included in this registration statement of which this prospectus is a part nor have we been able to obtain AHC's consent to the use of

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such report herein. As a result, in the event any persons seek to assert a claim against AHC under Section 11 of the Exchange Act for any untrue statement of a material fact contained in these financial statements or any omissions to state a material fact required to be stated therein, such persons will be barred. Accordingly, you may be unable to assert a claim against AHC under Section 11 of the Exchange Act for any purchases of the Company's Common Stock made in reliance upon statements set forth in the Form 10-K for the fiscal year ended July 31, 2004. In addition, the ability of AHC to satisfy any claims properly brought against it may be limited as a practical matter due to AHC's dissolution in 1996.

### USE OF PROCEEDS

We will not receive any proceeds from the sale of our Common Stock in this offering. Some of the shares of Common Stock to be sold in this offering have not yet been issued and will only be issued upon the exercise of warrants. We will receive estimated net proceeds of approximately \$25,173,314 if all such warrants are exercised. However, the warrants may not be exercised, in which event we would not receive any proceeds. We intend to use any proceeds received from the exercise of the warrants for general corporate purposes, including the funding of research and development activities. We expect to incur expenses of approximately \$40,000 in connection with this offering.

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### SELLING SECURITYHOLDERS

Alfacell has previously filed three Registration Statements, Nos. 333-38136, 333-89166 and 333-111101, in order to register shares of its Common Stock, as well as shares of Common Stock underlying warrants held by certain selling stockholders. Pursuant to Rule 429 under the Securities Act of 1933, in addition to serving as a post-effective amendment to Registration Statement No. 333-112865, this Registration Statement also serves as a post-effective amendment to Registration Statement Nos. 333-38136, 333-89166 and 333-111101. This Registration Statement eliminates those selling stockholders who have previously sold shares pursuant to such Registration Statements and also eliminates those selling stockholders to whom Alfacell no longer has registration obligations. On August 16, 2004, the Company filed post-effective amendments to Registration Statement Nos. 333-38136, 333-89166 and 333-111101 and a pre-effective amendment to Registration Statement No. 333-112865. Of the 12,380,717 shares registered pursuant to such August 16, 2004 post-effective and pre-effective amendments, as of October 15, 2004, 86,500 shares have either been sold pursuant to the previously filed Registration Statements or Alfacell is no longer required to register such shares. Accordingly, this Post-Effective Amendment Registration Statement carries forward from the four previously filed Registration Statements (i) 4,883,360 shares of Common Stock and (ii) 7,410,857 shares of Common Stock underlying warrants, for an aggregate of 12,294,217 shares of Common Stock. Alfacell issued such shares in various private placements from February 2000 through May 2004.

We are required to maintain the effectiveness of this registration statement for a period of two years from the date this registration statement is declared effective or such earlier date when all of the shares registered hereunder have been sold or may be sold without volume limitations pursuant to Rule 144(k) of the Securities Act of 1933, as amended.

### STOCK OWNERSHIP

The table below sets forth the number of shares of Common Stock,

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including those shares of Common Stock carried forward and offered by the selling stockholders pursuant to Registration Statement Nos. 333-38136, 333-89166 and 333-111101, that are:

- o owned beneficially by each of the selling stockholders;
- o offered by each selling stockholder pursuant to this prospectus;
- o to be owned beneficially by each selling stockholder after completion of the offering, assuming that all of the warrants and options held by the selling stockholders are exercised and all of the shares offered in this prospectus are sold and that none of the other shares held by the selling stockholders, if any, are sold; and
- o the percentage to be owned by each selling stockholder after completion of the offering, assuming that all of the warrants and options held by the selling stockholders are exercised and all of the shares offered in this prospectus are sold and that none of the other shares held by the selling stockholders, if any, are sold.

For purposes of this table each selling stockholder is deemed to beneficially own:

- o the shares of Common Stock underlying all warrants and options owned by the selling stockholders as of October 15, 2004 or which were exercisable within 60 days after October 15, 2004, unless otherwise indicated; and
- o the issued and outstanding shares of Common Stock owned by the selling stockholder as of October 15, 2004, unless otherwise indicated.

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Because the selling stockholders may offer all or some portion of the above-referenced securities under this prospectus or otherwise, no estimate can be given as to the amount or percentage that will be held by the selling stockholders upon termination of any sale. In addition, the selling stockholders identified above may have sold, transferred or otherwise disposed of all or a portion of such securities since the date on which information in this table is provided, in transactions exempt from the registration requirements of the Securities Act. Information about the selling stockholders may change from time to time. Any changed information will be set forth in prospectus supplements, if required.

Except as otherwise noted, none of such persons or entities has had any material relationship with us during the past three years.

In connection with the registration of the shares of Common Stock offered in this prospectus, we will supply prospectuses to the selling stockholders.

NAME (1)	SHARES OWNED PRIOR TO OFFERING (2)	TOTAL SHARES BEING OFFERED PURSUANT TO THIS PROSPECTUS	SHARES OWNED UPON COMPLETION OF OFFERING
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Anthony, Karen (4)	208,880	100,000	108,880



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Bachrodt, Patrick M.(5)	100,000	100,000	0
Basso Holdings, Ltd.(6)	227,273	227,273	0
Beto, David(7)	32,500	32,500	0
Bowen Gas Corporation(8)	92,000	92,000	0
Brown, Dennis(9)	163,800	100,000	63,800
Caasi, Krista J.(10)	5,000	5,000	0
Caasi, Santiago(11)	219,328	16,664	202,664
Conklin, Donald(12)	460,500	110,000	350,500
Danson, III Edward B. Family Trust(13)	120,000	50,000	70,000
DePeyster, Ashton(14)	155,553	61,110	94,443
DePeyster, Margo(15)	55,554	27,777	27,777
Dimzon, Delmer(16)	44,440	22,220	22,220
DKR Soundshore Strategic Holding Fund, Ltd(17)	227,273	227,273	0
DZS Computer Solutions, Inc.	197,056	50,000	147,056
Europa International, Inc.(18)	1,777,300	1,185,000	592,300
Falkner, R. Jerry	52,342	52,342	0
Furno, Robert C. and Mary E. Furno(19)	26,000	25,000	1,000
Furst, Thomas(20)	100,000	80,000	20,000
Garg, Mukul(21)	180,012	55,556	124,456
Goodwin, Todd(22)	74,999	33,333	41,666
Gostine, Mark	90,000	90,000	0
Hamblett, Michael(23)	17,819	13,819	4,000
Jacobson Living Trust(24)	287,000	175,000	112,000
Kalista JTWROS, Clifford and Phyllis(25)	82,308	51,308	31,000

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NAME(1)	SHARES OWNED PRIOR TO OFFERING(2)	TOTAL SHARES BEING OFFERED PURSUANT TO THIS PROSPECTUS	SHARES OWNED UPON COMPLETION OF OFFERING
Keating, A.J. Jr., M.D.	70,000	40,000	30,000
Knoll Capital Fund II(26)	1,621,880	1,185,000	436,880
Krogh, Jeffrey A.(27)	275,000	200,000	75,000
Krogh, Sally J.(28)	340,000	340,000	0
McCash Family Limited Partnership.(29)	7,671,331	1,506,570	6,164,761
McCash, Donna M. Irrevocable Trust(30)	1,258,538	177,222	1,081,316
McCash, James O.(31)	2,678,032	120,000	2,558,032
Muniz, Charles(32)	1,395,714	642,857	752,857
Muniz, Melba(33)	1,032,714	392,857	639,857
Neill, Carol(34)	154,200	120,000	34,200
Neill, Doug(35)	127,000	50,000	77,000
Number One Corporation	53,876	53,876	0
Patton, Eve M.(36)	656,667	266,667	390,000
Pawl, Lawrence E.	100,000	100,000	0
Pisani, B. Michael(37)	60,000	30,000	30,000
Plikerd, William D.(38)	100,000	100,000	0
Provenzano, Matthew J.	60,000	60,000	0
Samet, Roger(39)	420,000	50,000	370,000
Schiro, Anthony(40)	100,000	50,000	50,000
SF Capital Partners, Ltd.(41)	2,095,354	3,125,574	11,638
Shogen, Kuslima(42)	1,181,445	110,000	1,071,445
Sitao, Janine(43)	156,660	33,330	123,330
Steger Family Foundation(44)	55,556	55,556	0

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Stadler, Martin	180,000	110,000	70,000
Theresa M. Provenzano Revocable Living Trust U/A	40,000	40,000	0
Tweiten, Vicki K.(45)	40,000	40,000	0
VFT Special Ventures Ltd.(46)	60,533	60,533	0
Williams, Ira(47)	119,000	100,000	19,000
Wood, Scott	54,000	54,000	0
Zaumseil, Dean R.(48)	97,000	97,000	0
TOTAL	27,251,437	12,294,217	15,999,078

\* Represents less than one percent of Alfacell's outstanding Common Stock.

- (1) The last name of the individual selling stockholder is listed first.
- (2) Amounts represented include shares of Common Stock and shares of Common Stock underlying warrants that were registered pursuant to Registration Statements Nos. 333-38136, 333-89166 and 333-111101. Such shares are being offered pursuant to this combined prospectus, which serves as a post-effective amendment to such previously filed Registration Statements.

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- (3) The percentage of stock outstanding for each stockholder after the offering is calculated by dividing (i) (A) the number of shares of Common Stock deemed to be beneficially held by such stockholder as of October 15, 2004, minus (B) the number of shares being offered in this offering by such stockholder (including shares underlying options and warrants) by (i) the sum of (A) the number of shares of Common Stock outstanding as of October 15, 2004 plus (B) the number of shares of Common Stock issuable upon the exercise of options and warrants held by such stockholder which were exercisable as October 15, 2004 or which will be exercisable within 60 days after October 15, 2004 (including shares underlying options and warrants being offered in this offering).
- (4) Beneficial ownership includes an aggregate of 100,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (5) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (6) Beneficial ownership includes an aggregate of 113,637 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (7) Beneficial ownership includes an aggregate of 20,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (8) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (9) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.

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- (10) Beneficial ownership includes an aggregate of 5,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (11) Beneficial ownership includes an aggregate of 200,664 shares of Common Stock underlying warrants and options, of which 16,664 shares are being offered pursuant to this Registration Statement. Mr. Caasi is also the beneficial owner of an additional 5,000 shares of Common Stock underlying warrants which are held in the name of his minor daughter, Krista J. Caasi.
- (12) Mr. Conklin is a member of the Board of Directors of the Company. Beneficial ownership includes an aggregate of 185,000 shares of Common Stock underlying warrants and options, of which 110,000 shares are being offered pursuant to this Registration Statement.
- (13) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (14) Beneficial ownership includes an aggregate of 61,110 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement. Mr. DePeyster is also the beneficial owner of an additional 27,777 shares of Common Stock, and 27,777 shares of Common Stock underlying warrants which are held in the name of his wife, Margo DePeyster. Mr. DePeyster disclaims beneficial ownership of the shares held in the name of his wife.
- (15) Beneficial ownership includes an aggregate of 27,777 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement. Mrs. DePeyster is also the beneficial owner of an additional 94,443 shares of Common Stock, and 61,110 shares of Common Stock underlying warrants which are held in the name of her husband, Ashton DePeyster. Mrs. DePeyster disclaims beneficial ownership of the shares held in the name of her husband.
- (16) Beneficial ownership includes an aggregate of 22,220 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (17) Beneficial ownership includes an aggregate of 113,637 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (18) Beneficial ownership includes an aggregate of 592,500 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (19) Beneficial ownership includes an aggregate of 25,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (20) Beneficial ownership includes an aggregate of 40,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.

- (21) Beneficial ownership includes an aggregate of 55,556 shares of Common

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- Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (22) Beneficial ownership includes an aggregate of 33,333 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (23) Beneficial ownership includes an aggregate of 13,819 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (24) Beneficial ownership includes an aggregate of 125,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (25) Clifford and Phyllis Kalista of Clifford and Phyllis Kalista JTWROS, are employees of a broker-dealer and purchased all shares covered by this prospectus in the ordinary course of business and, at the time of the purchase of the shares to be resold, had no agreements or understandings, directly or indirectly, with any person to distribute such shares. Beneficial ownership includes an aggregate of 25,654 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (26) Beneficial ownership includes an aggregate of 592,500 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (27) Beneficial ownership includes an aggregate of 150,000 shares of Common Stock underlying warrants and options, of which 100,000 shares are being offered pursuant to this Registration Statement. Mr. Krogh is also the beneficial owner of an additional 140,000 shares of Common Stock, and 200,000 shares of Common Stock underlying warrants which are held in the name of his wife, Sally Krogh.
- (28) Beneficial ownership includes an aggregate of 200,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement. Mrs. Krogh is also the beneficial owner of an additional 125,000 shares of Common Stock and 150,000 shares of Common Stock underlying warrants and options, which are held in the name of her husband, Jeffrey Krogh.
- (29) Beneficial ownership includes an aggregate of 5,149,769 shares of Common Stock underlying warrants, of which 1,506,570 shares are being offered pursuant to this Registration Statement.
- (30) Beneficial ownership includes an aggregate of 688,019 shares of Common Stock underlying warrants, of which 177,222 shares are being offered pursuant to this Registration Statement. Mrs. McCash is also the beneficial owner of an additional 2,108,170 shares of Common Stock, and 569,862 shares of Common Stock underlying warrants which are held in the name of her husband, James McCash. Mrs. McCash disclaims beneficial ownership of the shares held in the name of her husband.
- (31) Beneficial ownership includes an aggregate of 569,862 shares of Common Stock underlying warrants, of which 120,000 shares are being offered pursuant to this Registration Statement. Mr. McCash is also the beneficial owner of an additional 570,519 shares of Common Stock, and 688,019 shares of Common Stock underlying warrants which are held in the name of his wife, Donna McCash Irrevocable Trust. Mr. McCash disclaims beneficial ownership of the shares held in the name of his wife.

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- (32) Beneficial ownership includes an aggregate of 642,857 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement. Mr. Muniz is also the beneficial owner of an additional 639,857 shares of Common Stock, and 392,857 shares of Common Stock underlying warrants which are held in the name of his wife, Melba Muniz. Mr. Muniz disclaims beneficial ownership of the shares held in the name of his wife.
- (33) Beneficial ownership includes an aggregate of 392,857 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement. Mrs. Muniz is also the beneficial owner of an additional 752,857 shares of Common Stock, and 642,857 shares of Common Stock underlying warrants which are held in the name of her husband, Charles Muniz. Mrs. Muniz disclaims beneficial ownership of the shares held in the name of her husband.
- (34) Beneficial ownership includes an aggregate of 60,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement. Mrs. Neill is also the beneficial owner of an additional 77,000 shares of Common Stock, and 50,000 shares of Common Stock underlying warrants which are held in the name of her husband, Doug Neill.
- (35) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement. Mr. Neill is also the beneficial owner of an

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- additional 94,200 shares of Common Stock, and 60,000 shares of Common Stock underlying warrants which are held in the name of his wife, Carol Neill.
- (36) Beneficial ownership includes an aggregate of 266,667 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (37) Beneficial ownership includes an aggregate of 30,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (38) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (39) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (40) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (41) SF Capital Partners Ltd., an affiliate of a broker-dealer, purchased all shares covered by this prospectus in the ordinary course of business and, at the time of the purchase of the shares to be resold, had no agreements or understandings, directly or indirectly, with any person to distribute such shares. Michael A. Roth and Brian J. Stark are the founding members and direct the management of Staro Asset Management, L.L.C., a Wisconsin limited liability company ("Staro"). Staro acts as investment manager and

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has sole power to direct the management of SF Capital Partners, Ltd., a British Virgin Islands company ("SF Capital"), which directly holds all of the shares of Common Stock. Through Staro, Messrs. Roth and Stark possess sole voting and dispositive power over all of the foregoing shares. Ownership prior to the offering excludes an aggregate of (i) 852,273 shares of Common Stock underlying warrants issued to SF Capital on September 3, 2003 and (ii) 189,585 shares of Common Stock underlying warrants issued to SF Capital on January 29, 2004, because the terms of such warrants preclude SF Capital from exercising the warrants if prior to or after such exercise, SF Capital or any of its affiliates beneficially own or will own in excess of 4.99% of the outstanding shares of Common Stock of the Company. The 852,273 shares of Common Stock underlying the September warrants were previously registered pursuant to Registration Statement No. 333-111101 and the 189,585 shares of Common Stock underlying the Additional Warrants are being registered pursuant to this Registration Statement.

- (42) Ms. Shogen is Chairman of the Board and Chief Executive Officer of the Company. Beneficial ownership includes an aggregate of 755,445 shares of Common Stock underlying warrants and options, of which 110,000 shares are being offered pursuant to this Registration Statement.
- (43) Beneficial ownership includes an aggregate of 108,330 shares of Common Stock underlying warrants and options, of which 33,330 shares are being offered pursuant to this Registration Statement.
- (44) Beneficial ownership includes an aggregate of 55,556 shares of Common Stock underlying warrants all of which are being offered pursuant to this Registration Statement.
- (45) Beneficial ownership includes an aggregate of 20,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (46) VFT Special Ventures Ltd., an affiliate of a broker-dealer, purchased all shares covered by this prospectus in the ordinary course of business and, at the time of the purchase of the shares to be resold, had no agreements or understandings, directly or indirectly, with any person to distribute such shares. Beneficial ownership includes an aggregate of 60,533 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (47) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.
- (48) Beneficial ownership includes an aggregate of 50,000 shares of Common Stock underlying warrants, all of which are being offered pursuant to this Registration Statement.

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### PLAN OF DISTRIBUTION

We are registering for resale by the selling stockholders and certain transferees a total of 12,294,217 shares of Common Stock, of which 4,883,360 are issued and outstanding and up to 7,410,857 are issuable upon exercise of warrants.

The Selling Stockholders and any of their pledgees, donees, assignees and

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successors-in-interest may, from time to time, sell any or all of their shares of Common Stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholders may use any one or more of the following methods when selling shares:

- o ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- o block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- o an exchange distribution in accordance with the rules of the applicable exchange;
- o privately negotiated transactions;
- o short sales;
- o broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- o a combination of any such methods of sale; and
- o any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The Selling Stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the Shares or Warrant Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of Common Stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Upon the Company being notified in writing by a Selling Stockholder that any material arrangement has been entered into with a broker-dealer for the sale of Common Stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such Selling Stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of Common Stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon the Company being notified in writing by a Selling Stockholder that a donee

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or pledge intends to sell more

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than 500 shares of Common Stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

The Selling Stockholders also may transfer the shares of Common Stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholders has represented and warranted to the Company that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the Common Stock.

The Company is required to pay all fees and expenses incident to the registration of the shares. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

### LEGAL MATTERS

The validity of the shares to be offered by this prospectus will be passed upon for us by Dorsey & Whitney, LLP, New York, New York.

### EXPERTS

Our financial statements as of and for the years ended July 31, 2004 and 2003 and for the period from August 24, 1981 (the date of inception) to July 31, 2004, incorporated in this registration statement by reference from the Alfacell Corporation Annual Report on Form 10-K for the year ended July 31, 2004 have been audited by J.H. Cohn LLP, independent registered public accounting firm, as stated in their report, which is incorporated herein by reference and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing. The report of J.H. Cohn LLP with respect to our financial statements from inception to July 31, 2004 is based on the reports of Armus Harrison & Co. and KPMG LLP, for the period from inception to July 31, 2002. As discussed in the Alfacell Corporation Annual Report on Form 10-K for the year ended July 31, 2004, Armus Harrison & Co. ceased performing accounting and auditing services for the Company in 1993 and subsequently dissolved and ceased all operations.

The financial statements for the year ended July 31, 2002, and the period from August 24, 1981 (the date of inception) to July 31, 2002, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The report of KPMG LLP with respect to our financial statements from inception to July 31, 2002 is based on the report of Armus Harrison & Co., incorporated by reference herein, for the period from inception to July 31, 1992. As discussed in the Alfacell Corporation Annual Report on Form 10-K for the year ended July 31, 2004, incorporated by reference herein, Armus Harrison & Co. ceased performing accounting and auditing services for the



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Company in 1993 and subsequently dissolved and ceased all operations.

The report of KPMG LLP covering the July 31, 2002 financial statements contains an explanatory paragraph that states that our recurring losses from operations, working capital deficit and

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limited liquid resources raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of that uncertainty.

Alfacell Corporation has agreed to indemnify and hold KPMG LLP (KPMG) harmless against and from any and all legal costs and expenses incurred by KPMG in successful defense of any legal action or proceeding that arises as a result of KPMG's consent to the incorporation by reference of its audit report on the Company's financial statements incorporated by reference in this registration statement.

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### WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC to register the sale of the shares of Common Stock offered by the selling shareholders under the Securities Act. This prospectus, which is a part of the registration statement, does not contain all of the information that is in the registration statement. Statements made in this prospectus as to the content of any contract, agreement or other document are not necessarily complete. Some contracts, agreements, or other documents are filed as exhibits to the registration statement or to a document incorporated by reference in this prospectus. In those cases, investors should refer to such exhibits for more complete descriptions.

We file annual, quarterly and special reports, proxy and information statements and other information with the SEC. The public may read and copy, at prescribed rates, any materials we file with the SEC, including the registration statement and its exhibits and any documents incorporated by reference into this prospectus, at the SEC's offices at: Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. 20549. For information on how to obtain such documents from the SEC, investors may telephone the SEC's Public Reference Room at 1-800-SEC-0330. The SEC Internet site at <http://www.sec.gov> contains materials that we file with the SEC in electronic version through the SEC's Electronic Data Gathering, Analysis and Retrieval (EDGAR) system.

We are allowed by the SEC to "incorporate by reference" information filed with the SEC, which means that we can disclose important information to people by referring them to other documents that we file with the SEC. The information incorporated by reference is considered to be part of this prospectus. We have filed the following documents with the SEC pursuant to the Exchange Act and are incorporating them by reference into this prospectus:

- (a) the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2004;
- (b) the Company's Quarterly Report on Form 10-Q for the quarter ended October 31, 2004;

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- (c) the Company's Current Reports on Form 8-K filed on September 9, 2004 and November 26, 2004; and
- (c) the description of Capital Stock contained in our Registration Statement on Form S-1 filed with the SEC (No. 333-112865).

We also incorporate all documents we subsequently file with the SEC pursuant to Section 13(a), 13(c), 14, or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of this offering. The information in these documents will update and supersede the information in this prospectus.

You can request a copy of these filings, at no cost, by writing or telephoning us at the following address:

Alfacell Corporation  
225 Belleville Avenue  
Bloomfield, New Jersey 07003  
(973) 748-8082